DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

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PREPROPOSAL CONFERENCE: RFP-NIH-NIAID-DAIDS-05-06,

HIV CLINICAL RESEARCH MANAGEMENT SUPPORT

- - -

Room 1205

6700B Rockledge Drive

Bethesda, Maryland

Monday, July 26, 2004

The conference was convened at 1:00 p.m.

SPEAKERS FROM NIAID:

JACQUELYN BURNS, HEALTH SCIENTIST ADMINISTRATOR FOR POLICY IN CLINICAL RESEARCH OPERATIONS

DR. JONATHAN KAGAN, DEPUTY DIRECTOR, DIVISION OF AIDS

DR. NANCY SAUNDERS, SCIENTIFIC REVIEW ADMINISTRATOR, SCIENTIFIC REVIEW PROGRAM

BARBARA SHADRICK, ACTING BRANCH CHIEF, RESEARCH RESOURCES CONTRACTS BRANCH, CONTRACT MANAGEMENT PROGRAM, DEA

ELIZABETH SHANAHAN, CONTRACTING OFFICER RESEARCH RESOURCES CONTRACTS BRANCH, CONTRACT MANAGEMENT PROGRAM, DEA

ATTENDEES:

PAUL AMSTELL	GENE BAYMAN
NANCY BLUSTEIN	JOHN BOGDAR
SAM BOZEMAN	MARK BRADSHAW
MATT BROWN	LAURENCE M. BUTTER

ATTENDEES: (Continued)

TONY CARITA	MEGAN CAYE
MIKE CHANEY	LISA CHATTERSEE
VARLA CLEMENT	DON COLLIE
OREN COHEN	LISA COLEMAN
FRANK COMBS	GREG DAVIS
RONALD L. DEAN	KATE FORTNEY
CARL FRETTS	FRANCIS HEILIG
TOM HILTKE	HORTENCIA HORNBEAK
JOHN HUDAK	MATTHEW KIRKLY
JONATHAN KIRSTEN	STUART KRAMER
CHERYL LAPHAM	MARK LESNICH
KATHLEEN McCARL	ANDREW MILNE
KRISTEN MONLIN	TERRY E. MYERS
CAROL NESEL	SOPHIE PARKER
DOMINIC REEVES	BETH ROY
KEN SANTURA	FELIX E. SCHACH
RONNY SCHNEL	RICH SHEA
KENNY SHIN	B. SMITH
KRISTY SPIVEY	DAN STABLEIN
CHRIS STATHES	BROCK THOMPSON
BOB VIT	DOUG WATT

P R O C E E D I N G S

(1:00 p.m.)

MS. SHANAHAN: Good afternoon. We've got quite a turnout here, and we're going to start on time in spite of all of our technological challenges up here.

I hope everybody signed in. If you haven't signed in, I'd appreciate if you could sign in before you leave.

I want to welcome all of you to the National Institute of -- I keep thinking my old Institute -- Allergy and Infectious Disease, and thank you for coming for the preproposal conference. I know it takes a lot of your time to come and participate in these things, but I do appreciate you investing the time and I think it'll be informative for you all as well as for us.

(Screen.)

All right. We have our agenda. First we're going to talk about the preproposal conference. We have some administrative items to go over. We have some people from the program office to discuss the enterprise system and the requirements in the statement of work. We have Nancy from the scientific review group. She's going to talk about the evaluation process, the technical evaluation process for your proposals.

Then I'm going to talk some more about some of

the things in the RFP. We have a lot of questions on the organizational conflicts of interest and issues, getting around the RFP. And we're going to talk about the schedule and go over some of your questions.

I have a handout back there. I think everybody got one. It's all the questions and answers that we received to date. The ones on the enterprise system, I don't have answers yet, but when I get those we'll post them.

Can everybody hear me? If I kind of fade out let me know, wave your hand or something, so you don't miss anything.

(Screen.)

The purpose of the preproposal conference. We don't do these very often. I thought it was important we do it for this acquisition because it's evolved a lot from the last time the RFP was out on the street and we have the core requirements and the non-core requirements, and I think there's been a lot of confusion about what it is that we wanted. So I think this is really beneficial that we have a face to face conversation and have the ability to exchange our ideas and discuss what is really important to us.

(Screen.)

In case you haven't met me or talked to me on

the phone, my name is Elizabeth Shanahan. I'm the contracting officer.

Today is not the only opportunity that you're going to have to ask questions. What's going to happen is once a week I'm going to be posting answers to the questions. It's going to be under the same amendment. I'm not going to keep issuing one amendment after the other. So it will be under the same amendment that I first answered your questions.

A transcript of today's meeting as well as the slides and the list of attendees is going to be posted on the web.

(Screen.)

When you're asking me questions and you're submitting questions, we would like you to be very careful and don't disclose any of your business strategies to me in your questions. I can't -- I wouldn't possibly know that that was your proprietary information and I have to post all the questions that I receive along with all of the answers.

As far as questions today, what we are going to do is we are going to have different people talking. Jackie and Nancy are going to talk and Jonathan Kagan is going to speak with you about the enterprise system. What I'd like for you to do at the end -- just hold your

questions to the end of each segment, because we're having this transcribed and it's going to be very difficult to stop and start. It'll mess up the flow of our presentation.

We also -- I have to tell you, we may not be able to answer all of your questions today because of the time constraints, and we want to give you a thoughtful and thorough answer. So there is a pretty good likelihood that we're going to just tell you we're not going to be able to answer your question today, but we will answer it and put the response on the web along with your questions.

(Screen.)

I think I've already talked about this. Our exchanges are going to be posted on the web. After the release of the solicitation, which has already happened obviously, I'm going to be your focal point if you need to contact me to submit your questions. Even if they're technical, they need to come through me.

VOICE: Could you speak just a little bit louder?

MS. SHANAHAN: Sure.

Jackie and Jonathan, you guys, do you have an order that you're going to go?

DR. BURNS: He's going to go first.

MS. SHANAHAN: Okay. We have lots of our staff

here to talk with you today. This is Dr. Kagan. He's the Deputy Director for the Division of AIDS.

Is Dr. Haffner here?

DR. BURNS: No, he wasn't able to come.

MS. SHANAHAN: Pam Scanlon, I'd like to also introduce her. She's the Branch Chief for the Clinical Research Resources Branch and this contract will reside in her branch. She's way back there.

And Jackie Burns. She is going to be the Project Officer for this acquisition. And Dr. Nancy Saunders, she's the Scientific Review Administrator in the Scientific Review Program and she's going to be responsible for the review of this proposal, of your proposals. And this is Barbara Shadrick.

MS. SHADRICK: Hi. Nice to meet you. Thank you so much for coming.

MS. SHANAHAN: She's my boss. She's the Acting Branch Chief for the Research Resource Contract Branch.

And there's Jonathan.

DR. KAGAN: Thanks, everybody, for coming.

I want to spend a few minutes talking to you, not about the RFP but about the environment of research that the RFP is designed to solicit the contract to support. So it's going to be the sea in which a successful offeror or offerors would find themselves

carrying out the work that is laid out in the RFP. So everybody kind of get a sense of what that's about.

I'm going to blow through some material that a couple of you have seen before. The point of it is not to understand every detail. The point of it is for you all to get the 20,000 foot view of the Division of AIDS' clinical research programs, the major programs that are going to be the ones that, if successful, you would have a lot of interaction with. So these are going to be groups of investigators. There will of course be smaller entities of clinical research that I'm not going to really capture here today. I'm going to be focusing on our big clinical trials programs because that's the bullseye.

So stop me if I say something that you really kind of don't get at all, but let me know. But if you can hold the questions until the end. If you feel like there are things that you want to ask for a matter of clarification or something, then hang with me until the end, because maybe some of those questions will actually get answered.

I don't know if I can control these things so that I can stand out of these people's way. Does this have any remote on it?

MS. SHADRICK: No, just a mouse.

DR. KAGAN: You guys should have told me. I

have those little gizmos. Well, I'll try to move around, but just tell me if you can't see.

(Screen.)

So, if you haven't already been made aware or are just kind of on the outside of things, the Division of AIDS is currently in the process of recompeting its entire clinical research network program. If that's not familiar to you, suffice it to say that we run seven clinical trials networks that cover the gamut of HIV-AIDS clinical research from prevention through treatment, including vaccines, non-vaccine forms of prevention, therapeutics, antiretrovirals, treatments for opportunistic diseases, immune-based treatments. We do research in adults and children, both in this country and outside of this country.

So we have a very, very comprehensive program. We have decided that, as opposed to the way that we have done things in the past, where we separately and individually renewed each of those programs through their own individual solicitation, we've decided to renew all those programs at the same time under a single umbrella solicitation.

So what we are going to be doing is actually making our investigators who do this research compete against each other, not only between areas. So in other

words, a very good application for a vaccine project will actually be going head to head with a very good application for a therapeutic project. Yes, we are comparing apples and oranges, but we think that's part of what we need to do.

We will also see applications coming in, we expect, where applicant groups apply to do the same kinds of research, and we'll try to figure out which is the best.

So this is something never been done by us and to our knowledge nobody at NIH has ever attempted to put a program of this massive scale -- it's about $300 to $400 million a year up -- for competition under a single umbrella. And I know many of my colleagues from the Division of AIDS and the Division of Extramural Activities are here and we're all cringing as we say this, but, you know, that's what we get paid to do. At the NIAID, you do good stuff.

(Screen.)

So what do we want to do in this whole competition thing? These are the objectives that we are trying to achieve. We have many groups who want to coordinate the leadership. There can be roles for this RFP, this ensuing contract, to help us coordinate this leadership.

We want to get increased accountability out of the networks, which a lot of that's going to relate to how they make their decisions and how they spend their money. The communication that needs to take place between these network leaders is something that can be facilitated by this award. We want to coordinate development of our sites, especially in resource-poor locations, that can be both in the United States -- there are resource-poor settings in this country -- just look around and you'll see them -- as well as the resource-poor settings in the developing world.

All of these objectives, the reason I'm going through them is because they're relevant to activities that the successful offeror will do: sharing laboratory resources and protocols, establishing common data elements. We currently have four data centers that support these seven current networks. These data centers, we'd like them to be able to work much more interchangeably so that we could do cross-enrollment across protocols, across different groups, and we won't be as stymied as we currently are by the different data systems and case report forms and status definitions and things like that that keep the groups from being able to work together.

Coordination of specimen management, because we

are not doing just your typical drug company trials in these studies. We collect a lot of biological specimens from subjects in these protocols, because we bank them and reuse them and reuse them for a lot of purposes that are very scientific. And some of the most valuable resources that we get out of our protocols are often the specimens that we have from the subjects.

Training needs. All of our networks have training needs, and up to this point they've tried among themselves to try and share and coordinate these activities, but this is something that they need help with.

The coordinated acquisition of products for clinical trials and the distribution and provision of those products to the trial sites is something that's going to be a challenge.

Coordinating of inter-network meetings. You can imagine, we have seven networks. They each meet three times a year. If we actually really want these folks to be talking to each other 21 meetings a year, it's hard to imagine that they're actually going to have any time at their home institutions doing what we're paying them to do. Maybe they can actually meet on the airplane.

Then we're looking for overall greater efficiency with all of our resources. And when I say

that, I mean both -- not just the dollars. Of course we want to be more efficient with the dollars. We have to be. But greater efficiency with the human resources. People are stretched very, very thin and we realize that the money is not as actually a limiting resource as the human capital of this research.

I have another meaning of "efficiency" which I think that a successful offeror can help with, and that is kind of the efficiency that I'm referring to when we talk about things like establishing common data elements among the different data centers. When you're able to do that, then you're able to do better cross-group analyses. You're able to take bigger looks at your data, because you're not stymied as much by different variations in how this assay was done in this group or that done in that group, and so we can't see big trends or we lose the ability to do that.

There's a scientific efficiency gained by thinking smart about what are the things in these networks that really do need to be done differently because their science is different and what are the things that actually don't need to be done differently, it's just that they got that way because the networks kind of were allowed to go their own way for so long.

(Screen.)

So I'm going to blow through the rest of this. That was what I really wanted to get to. This is all kind of to give you a primer of the clinical trials networks. The networks are all going to -- and these are the networks that want to be funded starting in 2006 -- are going to have to respond to an RFA where they see those, in a lot more detail of course, identified as the areas of research that we are looking to see covered.

These two are both to a large extent in the area of therapeutics. This one is around really bringing new strategies, new approaches to treatment, whereas this one is more about figuring out how best to use treatments that we have in particular subject populations and, as we say, optimize the clinical management of subjects.

These I think are all fairly self-explanatory -- MTCT, microbicides, vaccines. This one, which looks kind of like a grab-bag, is the part where we say it's the other forms of prevention research that are not these three. So that would include the use of antiretrovirals as a way of preventing infection, treatment of STI's, behavioral interventions, etcetera.

So those are the big areas that we're going to be asking our groups to respond to. I just kind of wanted to show you that we are not population-driven in our RFA. Our RFA is science-driven. We'll be accepting applicant

groups to tell us what populations they have access to and in which they can carry out this research.

(Screen.)

I want to show you quickly, how would these applicant networks actually apply to this proposal. You see those are the areas of science and then what would happen is that each group would then pick areas of science from the science menu, and then what they would do is that process would go on and repeat itself and then we would get a series of applicant networks and then they would submit those applications.

Then, similarly, there would be a separate solicitation for sites that want to participate in these networks. The sites would of course have access to the knowledge about what the applicant networks were proposing, what kind of research they were proposing to do. Then sites would similarly identify their areas of scientific expertise, as represented by those circles. They would list, they would identify their populations, their trial capacity, who they want to partner with in the U.S. or internationally. Ignore the word "domestic" on the top bar because we're combining the solicitation of the domestic and international sites into a single RFA.

They'll list their preferred network affiliations, and if they're developing country sites they

will also be able to list their capacity expansion plans so that they can get, if they score well, they can get support for that.

Then how do the clinical trials networks get formed? If you can imagine now, through these two separate solicitations, one for the leadership groups which I showed you, those floating Necco wafers, and the other one was for the sites. Then what we end up with is this diagram.

So there at the top you have an example of three applicant groups that got fundable scores, and then these sets of sites. Say all these have got fundable scores. Then what we do is, based on the scientific agendas of the applicant sites and the scientific agendas of the proposed groups, we match sites with leadership groups and out of that we form networks.

So I don't think you need to know really a whole lot more about this process right now, other than to see that this is kind of the general framework for how we go about putting networks together.

There is something I skipped out to try to be a little bit faster. Sorry, I know you can't see these, but these boxes in here, I'll read them to you. Each one says: "Operations, biostatistics, data management, and specialize laboratories."

We will provide each successful network with the resources for each of those particular areas. We believe that it's important that any funded network have the network capacity, those fundamental elements, so that it's not critically dependent on another network for these essential, but I'm almost going to call them housekeeping, functions. No network could ever design and carry out clinical trials without a biostatistical center. If they have to be sent to another group to actually compete for that other group's biostatistical resources, we don't think that would be a very effective way of expecting a network to be empowered to carry out its agenda.

So now we've got these networks funded and now I want to kind of show you the milieu around the networks, and that's where you all will come in. We expect that the networks are going to be managed to a large extent by a group that we'll call the managing partners committee. That's comprised of the network leaders.

We are going to use much more external scientific review than we have in the past. I probably won't explain much about that today. I will talk a little bit about an entity that we're forming called the community partners. This should probably look somewhat familiar to you. And I'm going to talk a little bit about the evaluation plan and I'm going to make the point that

this mega-effort is going to be leveraged and jointly, if we're successful, jointly managed with the other 23 institutes and centers among them at NIH that get AIDS funds and who want to participate in co-funding and co-managing this effort. I imagine in reality that'll probably boil down to five to ten other institutes and centers.

(Screen.)

So I just want to walk around this a little bit because there are a couple pieces of this you need to know about. There will be a managing partners committee. The purpose of this thing, if you don't want to read the slide, is that we are going to hold the network leaders, the chair of each of the resultant networks, responsible for coordinating the activities between the networks and for actually setting into place many of those objectives that I set up earlier.

Recall I talked about establishing common data elements between the data centers, working together to cooperate, to obtain drug from the drug industry or whatever other sources, the Global Fund or the PEPFAR program, etcetera.

So what we are going to be asking the network leaders to do in large measure is actually to step out of their whole former role, which was running their

individual networks, and to be holding hands with one another, making these networks work together.

Next I want to talk a little bit about community partners, because the community representatives, the community members -- that is, the people living with HIV, the people at risk for HIV, the people down on the ground who are confronting this disease in their communities and their families, etcetera -- these people play an extraordinarily important role in HIV-AIDS research.

And if this is new to you, it's okay. But the role of HIV research is very, very different than others, and largely in this respect. You might find a little bit of irony in this. As much as our networks have kind of gone their own ways, our current networks, in their different areas of science, so too to a large extent have the community members. So those who have been advocates for vaccines have gotten very focused in their area. Those who are advocates for pediatric research are very focused in their area.

The fact is the whole message we are trying to send with this unified approach to our clinical trials programs is that these artificial divisions that people have created around this aspect of AIDS research, like vaccines or microbicides or mother to child prevention, etcetera, they are all part of the research that needs to

be done in one comprehensive program. And that's what we're trying to push, we're trying to push our community representatives and our community leadership in that direction as well, so that we get away from the kind of parochial advocacy that, while it can be very effective in one sphere, does not -- poses problems, not only for subjects and for patients; it poses problems for research. So that's an attempt, and you will certainly hear a lot more about that.

(Screen.)

I'll skip over this slide. I've told you what's in it.

(Screen.)

I'm not really going to go over the contract. You'll hear a lot about that today.

(Screen.)

Jackie will cover that, so I'm going to skip that.

(Screen.)

The last thing I wanted to show you was that we are planning to run this whole enterprise in a much more performance-driven way than we ever have before. That's a big challenge for not only us at NIAID, but it's a challenge to kind of the way NIH has traditionally done business. Our sense, our notion, of evaluating the

successful research program is to count the number of successful re-competitions the grantee gets and count up the number of publications and, hey, they're doing great, they got refunded and they published a lot of papers.

Well, that's pretty appropriate for a number of kinds of basic research. We're going to be trying, though, to put in place in a clinical research program the kinds of metrics for assessing progress, some objective and some admittedly subjective. It is also on how are our networks doing individually, how is the whole enterprise doing collectively, at achieving the goals.

Evaluation expertise is something that we're going to need and that's a potential area of involvement for the contract.

The last thing I would say, just to reiterate, is that this is going to pose challenges, in addition to the fact that we're going to be trying to collaborate very closely with other institutes and centers. If we do it well it probably does not impact the contract terribly much. It does bring other people and other ideas into the fray, and it just means more voices to listen to.

So if you all like to be in an environment where you pretty much get to, you know, you talk to one person, you get one idea and then you run off with it, you should probably just check out now because that's not the world

of AIDS research. The world of AIDS research is a complex one with a lot of views. Very few of them are ever right or wrong, and a lot of it is around consensus-building and trying to stick with priorities, but being flexible enough to work around the realities that this disease brings to you.

So I'm sorry for going longer than I had hoped, but I hope that what this thing, this kind of presentation, gives you is a sense of where the contract fits into a larger world of clinical research programs. This is not to say that there will only be three networks. This is just, I didn't think it would be useful to put any more on here.

Lastly, a point I made at the very beginning is that we do support clinical research that is outside of these networks. And we would expect the resources of the successful contract to be brought to assist in ways, a number of potential ways, with respect to what we call those out of network or investigator-initiated clinical research, clinical trials that may come along. Currently it's not a huge part of our portfolio, but it could grow.

So I hope that's kind of a big picture. I'm sorry, Jackie and Barbara, for going so long today, but I can't figure out how to say it in fewer words.

Okay, questions?

(No response.)

DR. KAGAN: Good.

(Screen.)

DR. BURNS: I want to thank everybody for coming. My name is Jackie Burns and I have been the project officer for this contract from the very beginning, which was around three and a half years ago, and I've been at NIH for four years, but I've been working in HIV and AIDS research since 1989. So it's my calling.

I have been involved from an operational standpoint, and when I came to NIH I saw that there was a need, along with many other people, that there was a need to have flexibility and to be able to maneuver quickly and respond to the epidemic. So that kind of laid the framework, and it's been three very interesting years to get to this point.

So to get to today, to see you all here to hear about this, is very exciting for me.

(Screen.)

I want to show you where this fits in. I'm actually within a new program within the Division of AIDS. I'm not going to go into detail anything about the Division of AIDS. You're on your own. You can go to the web site. But within DAIDS there's the Office of the Director, there's a new program called the Office for

Policy and Clinical Research Operations. There's three branches -- Pharmaceutical Affairs Branch, which has contracts in it that handle pharmacy; there's the Regulatory Affairs Branch which has the regulatory compliance center; and then there's a new branch called the Clinical Research Resources Branch.

I introduced you to Pam Scanlon. She currently has two monitoring contracts within that branch. And this contract, which we're referring to as the CRS, will reside in the Office of the Director within OPCRO. And you see the three scientific programs that Jonathan Kagan talked about. I'm not going to go into any detail, but the CRS is a division-wide contract, a division-wide resource that will serve the needs of each of these programs.

(Screen.)

I think Jon gave a real good setup for me for the current environment. These are interesting times. We have the recompetition of the networks coming up and that's going to require additional support, and I think you all saw that from Jon's slides. We have a very growing clinical trials portfolio that's growing from the network perspective and from the non-network perspective.

There's an ongoing need for additional international infrastructure. I think just coming off of the International AIDS Conference, we all know that

there's a tremendous need, and the need for it is in the international setting. So this is the environment that we at DAIDS are operating under and we want this contract to help.

For us, which is one of the things which was very difficult for me to communicate to you all in the RFP, is that we have a lot of unknowns. We're not like a pharmaceutical company where we have our pipeline and we can tell you that there's ten products and we expect this many to be in phase 2. That's just not the way it works here.

We have a portfolio that is much larger than many pharmaceutical companies, but anyone that's worked on a contract with the Division of AIDS will know that there are many unknowns. We could just be sitting there and two weeks later a big investigator-initiated trial can walk in the door and suddenly we have to support that.

So we need -- we have a lot of unknowns. I know that we did get questions on it. I tried to communicate it to you as best as I could that we're the CRS, we're going to need you all to be flexible, to be able to respond to the unknown.

(Screen.)

I'm showing you this. I don't think I need to say much else, but we're viewing the clinical research and

management support contract as a pillar of the next five to seven years. It is key to our future. And the Division of AIDS has called this contract the cornerstone of future research. So we are putting a lot of eggs in this basket and we're very excited about it.

(Screen.)

I wanted to give you all just a current snapshot of how much we do. As Jon said, there are seven networks. We also have programs. So we have over ten major programs or networks, and these can have 10, 15, 20, 30 trials associated with them. We're in over 40 countries. Right now we have -- and these are just estimates -- we have over 250 protocols that are either active or in development. We're in 790 sites and counting. We'll be in 800 in no time. One monitoring contractor this year completed 1200 monitoring visits. So this is a huge portfolio, and I think that says a lot as to where we are.

So what are we looking for? Well, we're looking for the best, obviously. We want a flexible mechanism that can support. You heard from Dr. Kagan. We need help with the inter-network coordination, basic site assessment, planning, management, and a contract that can help us provide sustainable presence for infrastructure.

We need the ability to respond to the unknowns. You're going to hear that a lot. There are unknowns in

our portfolio. We need a contractor that can rapidly partner with multiple entities. I know that there are some companies that partner more easily or better with others. We need a company that's going to be able to very rapidly partner.

And we need to be able to fulfil the unique needs of institutions and regions, and with that the emphasis is going to be primarily on international. These are just examples of how we might use the CRS contract.

Then we also talked about, Dr. Kagan mentioned the community advisory board. We see this contract as helping with that.

(Screen.)

We spent a couple years thinking about how this is going to be designed. This was not an easy RFP to come up with.

What we finally decided was that we would have a core set of functions and a non-core set of functions. The only known that I had to work with was I know that I had -- that the Director of the Division of AIDS said go and do this contract and make it so that it can do anything.

So it took a long time to get this to where it is. But we divided it into core functions and non-core functions. The core functions are: Research program

management, and those are the typical tasks that you associate with research program management. It's in the RFP. I don't think we need to go into detail.

Subcontracts acquisition and management. I view this one as probably the most important task here. If the offeror cannot do subcontracts in a clinical trial setting and in an international setting, then they will not be successful.

Also, technical oversight of all functions. We don't want a core that executes a subcontract and then doesn't give any oversight to the subcontractor, because then we could have a disaster. So we expect for the core to have a working technical knowledge of what they're doing.

So we divide it into the core and the non-core. Now, with the non-core, those functions can be competed even by the successful offeror. So it could be in-house work or by a subcontractor, and that would be a conversation that would take place between the others and the contractor.

The non-core include just a broad spectrum of clinical research management. Just in a nutshell, it's providing services, phase 1 through phase 3. Just in your mind you all should have been doing clinical trials. Think of every service that you can with a phase 1 through

phase 3 trial, and that would come into a non-core set of functions.

(Screen.)

So what's the desired outcome? The hands up here are supposed to signal everyone working together. But as I look at it more and more, I started thinking of lots of other ways to look at that. But I want you all to look at that in a positive way. I started thinking, well, everybody's grabbing at something or gridlock or whatever. But I want you to think of it as a partnering way.

But anyway, so our desired outcome is that we have the world's most flexible mechanism that will allow us to respond to the HIV-AIDS epidemic. We want a contract that can facilitate the integration of the networks and investigators, what you saw from Dr. Kagan. That's not going to be an easy process and we want this contractor to be able to get in there and help.

There's probably going to be harmonization of procedures, standardizations of SOP's at sites. We need somebody with a can-do attitude and pretty much that can handle this, because these are going to be very, very senior scientific personnel that are going to suddenly be put in a rather new environment.

If I could just add, promoting standardization. We want help to promote standardization within the

Division of AIDS, too. One of the things we want is a seamless involvement between CRS and working with all the networks. I know that's going to take a while to achieve. We also are going to have the networks approve the work product. The networks have been fully briefed on this contract for I guess about a year now, so they know a fair amount about it, and they feel that they want to -- they're going to be the recipients of a lot of work from this contract, so they want to feel like they will have, are involved in it. So they will certainly get their input on work product.

If for instance a deliverable is provide a training session, whatever network it was for, we would get their input as to how that worked.

What else do we want? We want what anyone that is doing HIV and AIDS research wants and that is a sustainable clinical trial research infrastructure all over the world. And of course, last but not least, we want satisfied customers, both internal and external.

(Screen.)

Now, we're going to draw your attention to one thing within the RFP. I want you all to really think about this. I have given you all phase 3 metrics in the RFP and we've asked for a case study, and this is very, very important. So when you go back tonight, whatever,

and look at the phase 3 again, look at the instructions and give me and the Division of AIDS everything you've got. Tell us how you would do it, what sets you apart from the rest. Describe how you would use your own internal teams, how you would use subcontractors. You've gotten a lot of information from me and from Kagan and you'll get information also from the scientific review. So use that. Use that and present a case study: This is how we would do your phase 3 trial. And everyone has the same metrics, so you're on a level playing field.

(Screen.)

Now, the last thing I want to do is -- again, I think this is not an easy concept to get. So trying to make this meeting useful for you all, I tried to think of three scenarios of how this contract might be used. I want to tell you, do not pay attention to the task here (indicating). I don't want anyone to get hung up on that. Just pretend it's a task.

This first task, we want a QA audit, we want a one-time QA audit at lots of sites, because we have over 50 investigator studies and we want to know what those investigators are doing. They've been monitored, but we'd like some QA. So we've got the contract in place, so I sit down with the chosen offeror who's now the contractor, define the task to them, and we talk about it.

The core says: You know what; we can do that task within our organization. And so we all agree with it, that's great. So they determine it can be done 100 percent within the company. Then we go through the procedure which is outlined in your RFP and this is confirmed with the DAIDS. We have a cost estimate and a proposal and it's approved. This should be -- we will streamline this process.

So your internal staff goes out, does the QA. You've got to have monitoring staff who are unknown to each site. We give that -- we've given you some parameters. So your team performs the visits, writes up the visits, and you give it to the Division of AIDS.

So that's one way that this could be used.

(Screen.)

Now, the second is a mixed scenario, meaning that part of your staff as well as a sub will work together. So the task is we have training modules, wonderful training modules, but let's say we want to look at all of our training modules because we are moving toward standardization. So we say, go and inventory our training modules.

So we need -- and this one gets mixed because the contractor says: Okay, we can do it; I have three really good trainers, but you want me to go out to 40

sites. So given that scenario, we would propose that three of us do it here and we also get a subcontract. So we agree, it goes through the process. So this is an example of the core working, both in-house people as well as the subcontractor.

(Screen.)

Now, the third is another mixed scenario, but the emphasis on it is on the sub. It's a huge task. It's a phase 3 trial and we want something really huge. So we've already talked to our other contractors. They don't have the resources for it. It's a high political profile. So we need something done and they're like, okay, well, we can't do this. We have a monitor here that can provide the oversight, but we can't do this; this is going to have to be subbed out.

So they go through the process. So this is primarily subbed out. So what the core would be doing at this point is only providing technical oversight. They would not be participating in the monitoring.

(Screen.)

So this is a visual overview. I don't know if this helps you at all. I really struggled as to how to help people understand. The yellow represents the CRS contract, always with technical oversight. So three tasks have come in and those represent new in-house work, so

those are all being done by the CRS. A couple of more tasks come in, these are mixed, so you've got the yellow for the oversight with the subcontract, and then you have yellow because you also have people here from the CRS doing it. So it's a mixed team of both the core, prime, and the subcontractors.

Then the third scenario that I talked about is some large tasks come in and they are tasks that are done primarily by a subcontractor, with oversight -- you see the yellow at the top -- by the CRS. So this is like a snapshot at the time of what could be going on in this contract at any time.

So you can see why research program management is really, really important and you can see why subcontracts are really, really important. And you can see the technical oversight is an absolute must.

(Screen.)

So I think I've driven this point home, is what we want with the CRS contract is flexibility to respond rapidly and expertly, to respond to the demands and needs of the DAIDS international portfolio.

I want to thank you all for your time and attention through this. Your contributions can have a significant and lasting positive impact on the HIV-AIDS epidemic, which is very important to us. So thank you for

coming.

I think we're going to hold questions to the end. That's my understanding.

MS. SHADRICK: Maybe we should see if they have questions, take a few questions.

DR. BURNS: Do you all have any questions now, now that it's fresh in your mind?

(No response.)

DR. BURNS: I will tell you that I did work for CRO for two years, so I do understand CRO-speak. So if we have any CRO's in the audience --

(No response.)

DR. BURNS: Did I explain everything? It took me three years to figure this out, so if you all got it then that's really good.

Yes?

QUESTION: How do you propose that this group is going to interact with the various operating groups for each of the networks?

DR. BURNS: They will interact. It will depend on the task and it will be very much like when, with the HVTN coming in, they have to establish a link with PBD. Their data center has to establish a link, and we expect for them to work together, so it's going to take cooperation on everybody's part. But in the RFP it is

driven home that you're going to be working with these other contractors.

Did you have a question?

QUESTION: I have a question. Part of the RFP is talking about, for instance, discussion on human subjects. But we're not responding to any specific trial.

DR. BURNS: Right.

QUESTION: And it's kind of difficult to figure out where you're going with that and what you're looking for with respect to a response to human tissues or treatment of human subjects when you're not really dealing with the specific study.

DR. BURNS: I would have to defer.

MS. SHADRICK: Do you want me to take that?

DR. BURNS: Yes, I will have to defer.

MS. SHADRICK: That's always a tricky issue with the resource support contracts because you're not dealing directly with human subjects, but what you may be dealing with are the materials or the specimens or the samples that are being obtained by these study sites. So if they are crossing your hands, you may have to assure that they were obtained in accordance with the OHRP regulations and guidelines, that the proper clearances were obtained, the consent forms were done properly. So that will be what you'll have to demonstrate in your proposal, how you will

make sure that any information that crosses your path, whether it be the actual sample or specimen or the data from that, you have to assure that it was collected properly.

Does that answer your question?

QUESTION: Yes. So you're just looking more or less for a really generic response?

DR. BURNS: Yes.

MS. SHADRICK: Yes. If I'm not mistaken, though, wasn't there a place in the RFP where they were talking about nurses actually collecting blood if necessary?

DR. BURNS: There is something in there that talks about that we want to have the capability to, if we need to, go out to sites. This was a request from the vaccines group to be able to survey sites and help characterize sites. So there might be a request through the CRS contract to go and assist a principal investigator.

You'll need to remember that there's always going to be an investigator at any of these sites. You do not furnish the investigators. There will be DAIDS-funded investigators at these sites. So the investigator may say: I've got -- I need to take blood samples; we're going to follow the appropriate informed consent, all the

international procedures and everything else. So there might be a time where we might ask you to do that. It might not be blood samples. It might just be surveys. But the site may be short of personnel or other resources and they may ask the CRS to help out. But there would be someone else giving scientific direction.

DR. SHANAHAN: Jackie, would the site then be responsible for getting the human subjects consent?

DR. BURNS: The site would be responsible for getting that, yes.

Do you all understand the concept? It's okay to say no, because I'm really curious. This has not been an easy -- this has not been an easy concept to tease the core and the non-core out. If I don't have any questions because you all really get it -- this is unusual in a way. This is different and this is big. This is going to be like the largest contract we've ever done. So there's a lot riding on this.

So if you have any questions, you can always follow up with an e-mail within a reasonable time to Betty. You can't communicate with me, but you can communicate with Betty.

So that's it.

MS. SHADRICK: We assume that once you get into developing your proposal you're definitely going to come

across questions and issues, and we will be available to provide answers.

Nancy Saunders is with the Scientific Review Program and she's going to give an overview on our peer review process and what we'll be going through in analyzing and reviewing any proposals that are submitted.

DR. SAUNDERS: Good afternoon, and I'll just reiterate what they've already said and thank you all for coming. I hope that I'm going to be able to give you an overview of the review process and tell you what the reviewers are looking for, so that you'll then go home with some take-home messages that are going to help you to present yourselves well to the review panel and score well.

First, I'd like to introduce to you -- I won't be working on this alone in review. There's another SRA here, Dr. Cheryl Lapham, who's going to be working with me. She's in the back of the room. Also my Branch Chief, Dr. Dianne Tingley, is here today. She has a great deal of experience with the AIDS initiatives and so she will be my resource person. And our Program Chief, Dr. Hortencia Hornbeak, is here.

As the review person, my role in this initiative is a very focused time period. The time period of our work is from the time that your proposals are received and

when we finish the paperwork describing the results of the review. So my four primary responsibilities to both the NIH and to all of you who may be offerors is that first I'm going to form a review panel of technical reviewers who have all the expertise necessary to evaluate your proposals. I'll guide these experts through our review process and make sure that I've ensured objectivity and fairness as well as compliance with the regulations that govern peer review, both the federal, the NIH, and the NIAID guidelines.

Finally, I will document the findings of the panel and present them to contracts and to the program officer so they can then move forward with the process.

My review panel is the first thing that we will be forming. We are going to find a diversity of expertise, and a primary component that we're looking for is a breadth of experience. We are going to try to find senior individuals who can do this for us. Because of the size of this, we understand that they will need to really understand what you are proposing to do. It's going to be a large amount of work.

Now, an important part that I wanted to talk about is that the reviewers must not be in conflict with the proposals. Our goal is to have a full review panel that is in conflict with none of the offerors. This is

going to be very difficult to do, again, because of the size of it.

Please remember one of the mandatory criteria: Do not name specifically any subcontractors. If you do that, anyone who is involved with those subcontractor then would be in conflict and we could not use them as reviewers, and that would reduce the pool of high-level expertise, experienced individuals that we could use for this. It will be much easier for us to find the right people.

Now, any kind of conflict would involve over the last three years a personal, a professional, or a financial interaction between you and another person or another institution. So if you are already interacting with someone you're going to be naming them because you want to show your experience and your own ability to perform this. Those people will definitely be in conflict with your proposal.

But if it's a different and separate relationship that we can clearly define to NIH, we can get a waiver and those people might, or someone at their institutions might, be able to review other proposals. There would be a conflict with your proposal. They would not see it. They would recuse themselves from that particular review.

So each situation is unique and will be carried

out. But again, please do not name or do not seek out your subcontractors at this time. Wait until you have received the contract if you do.

For the expertise that we're looking for for this, we are needing to find those who have a great deal of experience with management, oversight, and the integrity of clinical trials. We'll certainly be looking for those who have experience in HIV clinical trials, whether it's vaccines, therapeutics, possibly topical microbicides, opportunistic infections, and behavioral interventions.

We will be looking particularly for those who have worked in international resource-poor regions. But we will probably have some reviewers who have worked in domestic sites. Obviously that also will be part of it. And as Jonathan pointed out, yes, there are resource-poor areas in our own country.

We'll also look for those who are expert in contracting issues, both in the acquisition and management of contracts.

(Screen.)

Finally, we'll be looking for reviewers who have expertise in all those non-core functions. I threw a few of them up here: the regulatory issue, compliance. The pages on here may not be exactly what they are with your

RFP if you look at it, but they're all the non-core functions. There are a great deal of functions.

I separated out the part about database enterprise system because it is important. It's already been discussed. And please do remember that you will be interfacing with a great deal of people through the Division of AIDS and please show your expertise at doing that.

Next.

(Screen.)

What tools am I going to give these people to do this review and how will I be guiding them to evaluate the proposals that you send in? We always give our review panels a reviewer manual that we make for each review. Some of the information in it is generic information about NIAID and about the review process. But the specific information that I'm going to give them that has to do with your review is going to be the same information that you have. They will be dealing with the same information. We don't change the rules or the playing field in any way.

I'll be giving them the statement of work so they can see all the tasks that you'll be asked to address. They'll know the mandatory criteria, what is core, what is non-core. They will know that you are not to name any of your subs. Also, there are scoreable

technical evaluation criteria that will be found in here in section M. This is all after the statement of work, section M. These are the two most important parts.

This is bolded on purpose because the technical evaluation criteria will give the score for your proposal, and I'm going to go into that a little more. And you did just touch on the human subjects. And the recruitment of women, minorities, and children, we do want some information on that, you'll see, in the RFP.

We realize that there are going to be trials and that the PI of the trials will be making many decisions. But if you're dealing with data, you have to think about confidentiality. If you're dealing with recruitment, you have to think about the inclusion issues and the protection of people.

So I also will give them two other things, the two A's: the appendices -- notice I have "A"; that's your table of contents basically, the order we'd like to see it in. They will not see B. That's the ordering and evaluation of the business proposal. Our technical review panel does not see the business proposal, does not know any of the financial information that's involved.

Also, we'll be giving them appendices C, D, and E. These are more for reference. This is a lot of information that just will give them a handle on what's

going on in DAIDS; and also all the amendments that have to do with the technical proposal, but not with the business proposal, because they don't need that.

(Screen.)

Now, the technical evaluation criteria, that's in section M. Please consider writing your proposals to speak to these. This is 250 points, the maximum that anyone can get for their proposal. These are the most important components of the review.

If you can address the statement of work by doing a good job of evaluating, of fulfilling these criteria, you will have done what you need to do. Notice the scoring is the most important: first, the most points, 170 points for the methodology. That in turn is divided into four sections: first, 50 points is given for centralized management and contract transition; and then we have the provision of non-core functions and subcontract acquisition and management. Please read those two carefully and make sure you're understanding and addressing them as separate issues.

In one case you want to describe to the reviewers that you do understand what the non-core functions are and what you need to fulfil any of the tasks. And in the other you're showing that you know the procedures and the appropriate methodology for acquiring

and managing the subcontract.

Finally, the fourth part of this is another 40 part, and that is the phase 3 case study that Jackie already talked about. So that's within this 170 points, but it's 40 points alone.

Then there's another 40 points for the staff and their qualifications, for the organizational experience, the resources, and your facilities. Remember that we are giving our reviewers the technical proposal. This is what they're evaluating. They will not see the business proposal, so they're not evaluating budget.

But please be careful not to bury something in that business proposal that might speak to your understanding of the technical requirements. The simplest thing for me to say as an example is percent effort. They will need to know that you realize how important and how difficult something is and how much of a percent effort the personnel involved would need to accomplish it. So make sure that that can be found in the technical proposal. That's just one example. Just be aware that if you have something in the business proposal the reviewers will not see it.

(Screen.)

How do we go about this? When we form the panel and we get together next winter to do the evaluation, we

will review each proposal separately. Each proposal will be evaluated in reference to the technical evaluation criteria. They will not be evaluated in comparison to each other. In fact, part of my job at the table is to make sure that that does not happen. We are looking at each one. We maintain a level playing field.

If opinions shift as we go, I bring the panel back, with the help of the chairperson, to make sure that we keep the same criteria as we do each one.

We also ask that the panel members only review what is in front of them in the proposal. They can't just say, well, no, they didn't say that, but I know they can do it because I know the company. That is not an acceptable criteria on which to evaluate. So it has to be within the proposal if you want to have it evaluated and give you points.

We go through those scoreable criteria starting with that 170, that 50 that comes first. We will discuss that as a panel. There will be a few people who will have prepared the discussion points beforehand and they will begin and discuss it. Then everyone at the table discusses every proposal and evaluates every proposal. This is with the exception of the possibility that we may have a few conflicted reviewers. They will be a minority of the panel. We will maintain as consistent a panel as

possible to keep things even.

Okay, I said that they're all independent of each other only in reference to the technical criteria.

(Screen.)

As I've said, the reviewers will be experts in various and sundry fields, whether it's management or the acquisition of contracts. Each of them will be bringing to the table a different expertise and we will join, and that's why we have the discussion, for them to share their expertise, is for other people in the same field to ask more questions.

Those points will all come out in the discussion. But when they actually do the scoring to put a number to each of these criteria, we ask that they judge them holistically, take into account what each different type of person has said about it, to come to a number. And that is a very important concept in this.

When they've finished this and all the scores have been added up, the entire proposal has been evaluated, then we ask the question: Is it overall acceptable or unacceptable? Does the panel feel that, even though there will be weaknesses or things that they want you to try to improve on or discuss more thoroughly, does it look like you can fulfil the needs of this contract?

And if the answer is yes, it's acceptable and it will move forward. If they think that the offeror really didn't understand and can't do it, then it would be unacceptable and that would end the discussion at that point.

(Screen.)

So as I said, everyone has submitted evaluations. My documentation that I will send forward after the review to contracts will be all these evaluations that they sent in and my own summary and listing of the strengths and weaknesses that I take both from the written critiques and from the discussion at the table. So when I have got all this paperwork together, I will send it forward and they will move on, and that ends program, or contract -- no, that doesn't end you. I'm sorry to say, that ends me in review and my part in this, and they will move forward with it.

(Screen.)

I have some advice to give you. A lot of this I've already said, but let me say it again. I want to be repetitious so I know you're taking home the right message. Please, address all the technical evaluation criteria. 40 points is the maximum you'll get or 50 for any one of these. You'll want to get as many as you can, as high as you can. You can't just skip over something.

Remember that the technical proposal has to be complete. If the information is not in there, the reviewers will not receive it.

Give us good details. Tell us about your decisionmaking procedures. The reviewers are going to want to know what you mean if you just say something about your management style. Please, give us enough information that they really can grasp and understand what you're doing.

Also, provide the specifics. Now, I know this is going to be difficult because we don't want you to name subcontractors, but you should be able to say what you know you will need from a subcontractor and how you're going to go about getting it. So we have to have both of those things. Those are two separate criteria, and we have to ask you to do that without naming specific organizations who will do that for you.

Carefully and specifically address the mandatory criteria and all the task areas in the statement of work. Again, I will just repeat that we want you to be as specific as possible to fulfil all the criteria.

Again, human subjects issues. If you want to make a separate section to cover the human subjects issue, and just make sure it's a specific section, that's fine, because we're probably just going to look at it once and

that will cover it.

(Screen.)

Now, I've been telling you to be sure to give me details, to be sure to include this, to be sure. Now I'm going to give you your opposite problem. You've got 150 pages. The reviewers are not going to get 151 or 152 pages. So please, adhere to those limitations. That means you have to be as clear and concise as you possibly can to fit all the information from this very large initiative in your proposals.

It's important to make sure that your paper and electronic copies are identical. What that really is saying is you really need to carefully check everything you're doing. Do proofread, do cross-reference and validate. There is no do-over here. Once we've got it, that's it and that's what we're going to be looking at. So if you make little mistakes, it's going to be available right there for the reviewers to see.

I always recommend, first of all, just the proofreading. But if you can be ready in time and you have a colleague who can work with you, who hasn't seen it, a fresh pair of eyes is a wonderful proofreader. If you can get it done and say, here's the statement of work, here's the criteria, the 250 points they're going to evaluate me on; how did I do it, it's really going to be

helpful. You'll see any possible things that you just didn't see, you're so in bed with it.

Also, in your proofreading look for inconsistencies. If you say something on page 10 and you say something that contradicts that on page 98, trust me, the reviewers are going to see it. These are senior people. They are very busy, but they take this task very seriously and they work very hard, and they are going to notice those inconsistencies if you leave them there, and they won't be doing you any favors.

I think that's it. Do you have any questions?

(No response.)

These slides will be up on the web site if you want to get any of these details again.

(No response.)

Not a question in the group.

MS. SHANAHAN: Okay, back to the RFP.

(Screen.)

MS. SHANAHAN: I got a lot of questions on the organizational conflict of interests, and you guys need to review items 18 and 19 in section L. It talks about you have an established policy to address organizational conflicts of interest, that you're going to review, your own folks in your organization, their own interests, and have a plan how you're going to mitigate if any of those

conflicts exist.

Only you have -- you're the ones that are best suited to make the determination if you do have a conflict, and you need to use your own judgment to make a determination if it's going to preclude you from being able to compete in this acquisition.

What we're going to ask, and I am going to revise the RFP, is that if a conflict does exist I need you to submit a mitigation plan. I just need you to identify what your plans are, how you're going to reduce what you're going to do to avoid having these conflicts.

You're going to have to sign off on the reps and certs, I think it's item 27 in section K, that you do have an organizational conflict of interest policy in place and that you do have ways of avoiding this.

I got a lot of questions on this. Maybe you guys having everything in place and everything is fine, but it just seemed like there were lots and lots of questions on that.

(Screen.)

We'll skip that.

Oh, also, I've been asked, if you participate in this acquisition is that going to preclude you from being able to compete for any other acquisitions? I don't know. Generally, NIH contracts have a conflict of interest --

it's the same language, it's the same requirement. So you'll be addressing that on a case by case basis.

(Screen.)

Okay. I trust all of you have been on the web site and kind of worked your way around the RFP. We have sections B through H and I are a streamlined RFP. We don't have the full text of anything there. You need to click and it will take you to our web site, where the full text is.

It says -- you need to look at this because it contains articles and provisions that may be incorporated in any resultant contract. Section I is the same thing. You need to review that and make sure that you're comfortable with everything that's in there, because a lot of times people say, oh, I didn't look at that. Well, that's the meat of the contract, so it's really important that you do review that.

(Screen.)

Section J is nicely organized: a list about which attachments are required for submitting with your RFP, what's going to be incorporated in the contract. I especially like the one, the breakdown for proposed estimated costs. That's a really good template. Whoever put that together, it's been a real lifesaver.

We're going to ask you -- there's a proposal

intent response sheet. We use that for a number of different things. The scientific review program uses that. When you submit that and you say you intend to submit a proposal, they use that to facilitate organizing their review, because they want to make sure they've ruled out that there are going to be any conflicts with any of the reviewers and your organization. So that helps them plan their review.

It's also a mechanism for us giving you your password and for downloading your electronic proposal. I've gotten a lot of phone calls on the very last day of people saying: I don't have my password. So if you submit the proposal intent form that'll get that taken care of before it's time to submit your proposal.

(Screen.)

Section K, that's just the reps and certs. I think there are about 30 of them. You have to sign and certify each one. That's real important. I don't think that goes towards the page limitation, does it?

MS. SHADRICK: It's in the business proposal and we only need you to submit the one signed original. You don't need to submit multiple copies of it.

MS. SHANAHAN: Okay.

Section L, there's lots of information there, how to prepare your technical proposal and your business

proposal.

(Screen.)

Section M. You want to pay real close attention to section M. We do have a mandatory evaluation criteria and I think we've said it several times, but do not identify subcontractors that you plan on subcontracting with.

Also, I got a question about consultants. Don't identify the consultants because it will cause problems, and if you identify them then it will be nonresponsive to the RFP.

When you are preparing your proposal, you want to make -- really, be very careful that you pay attention to what the technical evaluation criteria, what the emphasis is on. I know we have other information in Appendix A and B. It's a table of contents. Those need to be revised. We weren't real clear and maybe provide some conflicting information. So in the amendment those are going to be -- we're going to straighten some of those things out.

But that table of contents will really help you organize your proposal. But you want to make sure that you address the evaluation criteria in section M.

(Screen.)

The appendices. A- we're going to revise. It's

intended to be helpful, but it kind of inserted some confusing information. Appendix B we got a lot -- those are the uniform budget assumptions. We've gotten a lot of questions about, can you give us estimates about this, or can you characterize this. We don't have any more information to give you any estimates. What we have is what's available. We're working with a lot of unknowns.

Appendices C, D, and E, those are the Division of AIDS clinical trial portfolio. Those are real helpful.

I don't know, do we have anything about the enterprise system in that discussion?

MS. SHADRICK: Yes.

MS. SHANAHAN: Okay.

(Screen.)

The acquisition schedule. These are general dates. It's a plan. We have a lot of external factors that somehow always seem to influence whether we're going to be able to award something on time. I think Jackie's used the term "flexibility." You're going to have to be flexible and we're going to have to be flexible in terms of trying to meet -- we are committed to meeting the award date. We're enthused about getting the contract awarded. So yes, you are going to have to be flexible.

If we kind of -- if there's a two-week slip in one direction or the other with just even the months that

are identified -- I like to give this to people because I always get phone calls about planning vacations and how we're going to do this or that. So I don't think we're going to be updating this. I mean, if there's a two-week slip I don't plan on updating the schedule.

So do you have any questions for me?

QUESTION: I have a question with respect to the small and disadvantaged businesses contract requirement to be submitted along with the proposal. For the core services, you're not required -- you can't subcontract out any of those activities. You have to perform those all in-house, according to the RFP. The amount of non-core services is technically unknown at this point in time, so it's kind of hard to put specific dollar values within a small and disadvantaged business plan when it can only be for non-core services, and there's also liquidated damages for performance against that small and small disadvantaged businesses contracting plan.

So it's kind of grey as to what you can put in there because it's for something that you haven't even quantified yet what it's going to be, because it can only be associated with non-core services.

MS. SHANAHAN: Okay.

MS. SHADRICK: Do you want me to take that one?

Repeat the question?

MS. SHANAHAN: Do you want to come up here and ask?

MS. SHADRICK: Let me summarize this because I know this is a big issue and I've thought about it myself. I think the dilemma here is that the non-core subcontractors are unknown, but we've given you a dollar amount to put in all your proposals for subcontracting for the non-core functions. What we're looking at in your subcontracting plan is you know the total value of your contract, including the non-core functions. You know the type of organizations that you may be dealing with, that provide the type of support we're looking for for the non-core functions. You know if they are primarily SDB's or hub zones or veteran-owned or whatever.

So I really believe you can project a certain percentage of the total dollar value of the contract, that your objective is to go out and do business with these types of subcontractors.

You're absolutely right, there is a liquidated damages issue with regards to not meeting your goals. But that plan is a plan to meet those goals. You are entitled during the course of the contract to revise your plan or to submit an explanation as to why you cannot meet those goals, and that's taken into consideration.

So it's a challenge, but I do believe that,

based on your demonstrated understanding of the community out there, that you will be able to achieve this and give us some good goals.

MS. SHANAHAN: You could shift between the different types of small businesses if it works, but you would have to tell us that that's the way it's going to fall out.

I think, what is it, they have to ensure their best effort.

MS. SHADRICK: The best efforts, right. And it may be a situation where there might be some multiple negotiations of this plan throughout the course of the contract. There's no reason why it can't be -- normally we don't like to readdress it, but this might be, there are so many other things unique about this contract, there's no reason why the subcontracting plan couldn't be unique also.

MS. SHANAHAN: We should be consistent.

(Laughter.)

QUESTION: You said that you were going to be doing some revisions and rewriting yourselves. Where is that going to fall into your time frame?

MS. SHANAHAN: Soon. We will do that soon.

QUESTION: Give or take two weeks?

MS. SHANAHAN: Yes.

QUESTION: Soon? Because you've got your proposals due in September.

MS. SHANAHAN: Oh, absolutely. I would say within the next couple of weeks, yes.

MS. SHADRICK: The schedule is that the transcript is going to be -- we're supposed to have the transcript in a week. Once we have the transcript in our hands, we can use that. We were actually anticipating that there might be some issues that had to be -- that were brought up at this meeting that had to be addressed. That hasn't been the case.

So really what we're concentrating on is the list of questions that you guys have already sent to us and we've already prepared answers. We're going to use that information to go in and make edits to the solicitation package. That will then be posted as an amendment with all those corrections. We will also post an amendment that will provide the transcript to everybody and we will post an amendment that includes all the Q and A, and that Q and A will be added to on a weekly basis as you submit more questions.

So our goal is to keep amending the RFP as it's needed up through September 10th. Once September 10th comes around, we're going to have to cut you off because then we need time to wrap it up.

MS. SHANAHAN: Yes. If you have burning questions, have them before September 10th.

QUESTION: When are the slides going to be available?

MS. SHANAHAN: I would suspect -- I would like to put this out there as soon as possible. I don't see any reason for not putting them up.

MS. SHADRICK: I can check with our network person and see if we can't get them and post it on the home page. It won't be on FedBizOps. We'll put it on our home page, the CRP home page with the solicitation.

MS. SHANAHAN: Any other questions?

(No response.)

MS. SHANAHAN: I'm sure you'll have more. You could always e-mail, e-mail them to me.

Somebody has left a cell phone out in the lobby with the guard. You might want to check your pockets and see if you're missing one. You can claim it out there.

Thank you so much for coming and we are pleased with the turnout, and I look forward to seeing a lot of proposals on this.

(Whereupon, at 2:33 p.m., the conference was adjourned.)